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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,246	07/28/2006	Alastair David Griffiths Lawson	13001011PCTUS	9639

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EXAMINER	
WEN, SHARON X	

ART UNIT	PAPER NUMBER
1644	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,246	LAWSON ET AL.	
	Examiner	Art Unit	
	Sharon Wen	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 12-20* is/are pending in the application.

4a) Of the above claim(s) *2,4,5,7,8 and 12-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 3, 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 02/14/2006, has been entered.

Claims 10-11 have been canceled.

Claims 1-9 and 12-20 are pending.

Election/Restrictions

2. Applicant's election without traverse of Group I and the following species:

a) "parts a) and b) or a) and c), or b) and c) are performed simultaneously";

b) "with at least one wash step"

c) "bringing said population into contact with an antibody that recognizes a marker which is essentially unique to those cells present in the population which are capable of producing an antibody, said antibody being attached to a first fluorescent label without additional step"; AND

d) Without all the steps recited in claims 7 and 15-18;

in the reply filed on 12/20/2007 is acknowledged.

Upon further consideration, the examination has been extended to include the species "without at least one wash step".

Claims 2, 4-5, 7-9, 12-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Invention/species, there being no allowable generic or linking claim.

Claims 1, 3 and 6 are currently under examination as they read on a method of enriching a population of cells which produce an antibody.

Priority

3. The domestic priority for claims 1, 3 and 6 is deemed the effective filing date of the PCT/GB04/03523, i.e., 08/12/2004.

Applicant's claim for foreign priority is acknowledged. Priority applications, 0319587.2, filed 08/20/2003 and 0402641.5, filed 02/06/2004, appear to have sufficient written support for claims 1, 3 and 6.

Applicant's amendment to the first line of specification to reflect his/her priority claim, filed 02/14/2006, is acknowledged and has been entered.

Information Disclosure Statement

4. The information disclosure statement (IDS) submitted on 06/05/2006 is being considered by the examiner.

Specification

5. Applicant is requested to review the application for spelling error, the use of trademarks, embedded hyperlinks and/or other form of browser-executable code (e.g., see page 20).

Trademarks should be capitalized wherever it appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1, 3 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Regarding the instant claim limitations, the specification does not appear to provide an adequate written description for all marker which is essentially unique to those cells present in the population because there is a lack of sufficient written description to support the claimed genus of the markers.

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C § 112, paragraph 1 "Written Description" requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by **disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure**, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4 pages 1099-1111, Friday January, 2001, See especially page 1106 3rd column).

The instant specification discloses a genus of "essentially unique markers" are those markers that are predominantly present on those cells capable of producing antibody compared to other cells, but not necessarily to the exclusion of all other cell types (see page 3 of the specification). However, the instant specification, as-filed, discloses only a limited number of species in this genus, i.e., CD5, CD9, CD10, CD19, CD20, CD21, CD22, CD45, and CD45 RC (see page 4 of the specification). These species do not a common structure drawn to a common function, i.e., essentially unique to antibody-producing cell. For example, CD45 is not limited to B cell, but also appears

on T cell. Therefore the specification does not provide sufficient written support for the genus of markers recited in the claims.

With regard to the genus of markers, the problem is that the instant specification fails to provide a disclosure of a genus of markers by disclosure of relevant, identifying characteristics coupled with a known or disclosed correlation between function and structure, i.e., which markers are essentially unique to the population of cells.

A skilled artisan cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus of the markers that exhibit this functional property.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.) Consequently, Applicant was not in possession of the instant claimed invention. See *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

Applicant is directed to the final Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, first paragraph "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. § 112 is severable from its enablement provision. (See page 1115.)

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1,3 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Chang (US Patent 5,213,960, see entire document).

Chang teaches an enrichment method using FACS comprising labeling a B cell marker with an antibody conjugated to a fluorescent label and the antigen of interest that is labeled with a second antibody conjugated to a fluorescent label (see entire document, in particular, see Abstract, Summary of the Invention and Claims 2-12).

In particular, Chang teaches labeling a marker which is essentially unique to B cells, e.g., CD19 or γ chain, κ or λ chains, and Fc receptor (see, e.g., column 5, lines 35-53) and also labeling the antibody that binds to the antigen of interest (see column 5, lines 25-34). Under the broadest reasonable interpretation of the claim, the prior art teaching meets the sequential steps recited in claim 3 of the present application because antibody labeling is to be done in a step-wise fashion.

Although Chang is silent about "at least one wash step" in the enrichment method, *per se*, in view of the disclosure of **washing solution** taught by Chang (see column 11, lines 55-60), one of ordinary skill in the art would have immediately envisaged a washing step because cell-labeling and FACS methods would inherently comprise wash steps.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1, 3 and 6 rejected under 35 U.S.C. 103(a) as being unpatentable over Chang (US Patent 5,213,960) in view of Brezinsky et al. (JIM 2003, 277:141-155, cited on IDS).

Chang reference has been discussed above.

Chang differs from the present claims in that it does not explicitly teach "at least one wash step" in the enrichment method. However, it would have been obvious to a person of ordinary skill in the art to include at least one wash step in the method of enriching a population of cells using FACS because it is well known at the time of the invention to include wash steps in any immunoassays.

For example, Brezinsky et al. teach washing antibody-producing cells before and after labeling in a method of enrichment FASC (see entire document, in particular, see page 143, paragraph bridging left and right columns).

Given that Chang teaches a washing solution in the assay (see column 11, lines 55-60) and that Brezinsky et al. also teach multiple washing steps in another FACS enrichment assay for antibody-producing cells, it would have been prima facie obvious to one of ordinary skill in the art to include the wash steps in the methods taught by the Chang reference.

One of skill in the art would have been motivated to wash the cells before and after labeling during the assays to reduce background signals.

Therefore, the invention, as a whole, was *prima facie* obvious to one of ordinary skill in the art, at the time the invention was made as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARON WEN whose telephone number is (571)270-3064. The examiner can normally be reached on Monday-Thursday, 8:30AM-6:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eileen O'Hara can be reached on (571)272-0878. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sharon Wen, Ph.D./
Examiner, Art Unit 1644
February 28, 2008

/Phillip Gambel/
Primary Examiner, Art Unit 1644